

REMARKS

This is an Amendment and Reply to the Office Action dated February 28, 2003. The Applicants respectfully request reconsideration and allowance of the application and the claims presently at issue in light of the remarks set forth herein.

1. Restriction Requirement

The Examiner has previously restricted and required election between the claims of Group I (claims 1-58), directed to a device, and the claims of Group II (claims 59-64), directed to a method of use. The Examiner further restricted Group I to three species: Species A (Figure 1); Species B (Figures 2-36(c)); and Species C (Figures 37-39). The Applicants provisionally elected with traverse the claims directed to Species A, which the Applicants maintain to be claims 1-58.

In the present office action, the Examiner has now indicated that claims 17, 24, 30 and 31 will not be examined because they read on Figure 2, and claims 28 and 37 will not be examined because, according to the Examiner, the description in the specification on page 16 indicates that they are related to another embodiment. The Applicants respectfully traverse the Examiner's position with respect to identification of claims directed to Species A and requests reconsideration.

Claims 17 and 30 are directed to an IV bag as the medication container and an IV drug as the medication. The Applicants submit that IV bags are clearly disclosed in Figure 1 and are known medication containers.

Claims 24 is directed to an infrared transmitter as the data transmitter on the personal digital assistant, and an infrared transceiver as the data port on the pump. The Applicants submit that an infrared transmitter is a known data transmitter and an infrared transceiver is a known data transceiver. As such, a search for a data transmitter would suffice for an infrared transmitter. Similarly, a search for a data transceiver would suffice for an infrared transceiver.

Claim 31 is directed to an infusion pump as the medication delivery device. The

Applicants submit that an infusion pump is a known medication delivery device. As such, a search for a medication delivery device would suffice for an infusion pump.

The Applicants respectfully request reconsideration of the Examiner's position with respect to claims 17, 24, 28, 30, 31 and 37.

2. Present Status of Patent Application

Claims 1-64 are pending in this application. Since the Examiner has made the restriction with respect to Species A final, i.e., Group I consisting of claims 1-58, the Applicants have cancelled without prejudice the claims of non-elected Group II, i.e., claims 59-64. The Examiner contends that claims 1-16, 18-23, 25-29, and 32-57 are directed to Species A and are therefore at issue.¹ The Applicants traverse the Examiner's contentions set forth in the present action and maintain that claims 1-58 are directed to Species A and therefore remain at issue.

3. Information Disclosure Statement

In the present office action, the Examiner has indicated that the Information Disclosure Statement filed on May 30, 2002 fails to comply with 37 C.F.R. 1.98, apparently because of the lack of a concise explanation of relevance or a translation for each of the foreign references listed therein that were crossed out by the Examiner. In addition, it appears that U.S. Re. 35,743 was not considered by the Examiner, although the Examiner did not indicate why it was not considered.

To address the Examiner's objection, the Applicants submit separately a Supplemental Disclosure Statement that now includes a concise explanation of relevance in English for each of the foreign references crossed out by the Examiner, with the exception of Taiwan Document No. 76107449 and German Document No. 9308204. A concise explanation of relevance in English for these references will be provided in a separate supplemental disclosure statement.

¹ Claim 58 is not addressed in the Election/Restrictions section of the present office action but has nevertheless been withdrawn from consideration. The Applicants submit that claim 58 should properly be considered with the remaining pending claims. Clarification from the Examiner is respectfully requested.

Additionally, a copy of U.S. Re. 35,743 has been included. Consideration of these references is respectfully requested.

4. Examiner's Rejections

In the present office action, the Examiner has rejected claims 1-3, 5, 9-11, 13-16, 18, 25-27, 29, 32, 33, 35, 38 and 42-52 under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Publication No. US 2001/0044731 A1 to Coffman et al. ("Coffman"). The Examiner also rejected claims 4, 6-8, 12, 19-23, 34, 36, 39, 40, 41 and 53 under 35 U.S.C. § 103(a) as being unpatentable over Coffman in view of U.S. Patent No. 6,021,392 to Lester et al. ("Lester").

5. Summary of Present Invention

The present invention is directed to a medication delivery system capable of communicating and matching prescribed medication data from a first label on a medication container holding the medication and patient data from a second label on a tag adapted to be worn by a patient. The first label also contains instruction of delivering the medication. The medication and patient data is provided in machine readable formats. The medication delivery system includes a medical device in communication with the medication container. The medical device is adapted to delivering the medication from the container to the patient. The medical device has a data port for receiving information. The system also includes a handheld computing device having means for reading the prescribed medication data and the patient data and comparing the data to confirm a match between the medication data and patient data. The handheld computing device has a transmitter capable of transmitting the medication delivery instruction from the handheld computing device to the medical device. The medical device is adapted to deliver the medication to the patient according to the instructions.

6. Reply to the Examiner's Rejections

The Applicant responds to the Examiner's rejections as follows:

a. Rejection of claims 1-3, 5, 9-11, 13-16, 18, 25-27, 29, 32, 33, 35, 38 and 42-52 under 35 U.S.C. § 102(b)

The Examiner has rejected claims 1-3, 5, 9-11, 13-16, 18, 25-27, 29, 32, 33, 35, 38 and 42-52 under 35 U.S.C. § 102(b) as being anticipated by Coffman. The Examiner contends that Coffman teaches a medical transaction carrier in communication with a caregiver, patient and medication via bar code labels and tags. The Examiner further contends that the communications between the various components of the system using wireless technology may utilize radio frequency electromagnetic radiation, infrared radiation, or other means. The Examiner cites to Coffman as providing for "closing the loop on drug delivery and validation that the right treatment has been given to the right patient."

The Applicants respectfully traverse the Examiner's rejection. While Coffman generally discloses a medication management drug delivery system, it does not disclose, nor does it teach or even suggest, a medication delivery system as claimed by the Applicants.

The Applicants invention as claimed in independent claim 1 requires, among other things, "a handheld computing device having means for reading the prescribed medication data and the patient data and comparing the data to confirm a match between the medication data and patient data, the handheld computing device having a transmitter capable of transmitting the medication delivery instruction from the handheld computing device to the medical device wherein the medical device is adapted to deliver the medication to the patient according to the instructions."

The Applicants invention as claimed in independent claim 16 requires, among other things, "a personal digital assistant having a bar code scanner thereon and a data transmitter thereon, the personal digital assistant is configured to scan the first bar code label and the second bar code label and compare data from the scanned labels to confirm a match between the medication data and the patient data, the personal digital assistant transmitter capable of

transmitting the predetermined set of pumping instructions (read from the label having the medication data) from the personal digital assistant to the infusion pump wherein the pump is adapted to deliver the medication to the patient according to the instructions.”

Independent claims 29 and 50 require, among other things, “a handheld computing device with means for reading the prescribed medication data (from a tag), the medication delivery instruction (from a tag), and the patient data (from a tag); means for storing the data; and means for communicating with other electronic devices.” Claims 29 and 50 further require that the handheld computing device reads “the prescribed medication data and the patient data, performs a matching check between the prescribed medication data and the patient data to confirm a match, and communicates the medication delivery instruction to the electronic medication delivery device to deliver the medication to the patient.”

Coffman, on the other hand, does not disclose a system utilizing a handheld device that is capable of reading the prescribed medication data from a tag or label, reading the patient data from a tag or label and comparing the data to confirm a match between the medication data and patient data. Furthermore, Coffman does not disclose a handheld device that reads medication delivery instructions from a tag or label and transmits them to a medication delivery device to deliver the medication to the patient. In the only embodiment of the Coffman system where a handheld device is utilized as the Medical Transaction Carrier (MTC), the handheld unit merely acts to deliver information, not read and process the information. Coffman states:

Once the medical transactions are assembled and available for access by the control system 40, specific infusion delivery protocols, medication limits, time-based medication constraints, and/or other patient's specific information comprising the medical transaction information may be transferred to the MTC 110. *** Once the specific information has been downloaded from the control system 40 into the MTC 110, the MTC is ready to accompany the medication to the patient area for treatment of the patient.

(Coffman, Paragraph [0061]).

Thus, the handheld unit of Coffman does not itself read data from tags or labels, nor does it compare data and process it. Indeed, Coffman does not disclose or suggest that the MTC even

has the capability to perform such tasks. It merely acts as a delivery conduit for information that has been downloaded from the system. In this respect, it is merely a passive device.

Based at least on the foregoing, the Applicants respectfully submit that Coffman does not disclose, nor does it teach or suggest the Applicants' claimed invention. Accordingly, independent claims 1, 16, 29 and 50, and dependent claims 2, 3, 5, 9-11, 13-15, 18, 25-27, 32, 33, 35, 38 and 42-49, 51 and 52, based on their dependence therefrom, should be allowable.

In addition to the distinctions set forth above, claims 27, 48 and 49 also distinguish patently over Coffman for the following reasons.

Claim 27 requires, among other things, that "the delivery channel of the infusion pump has a third label containing channel data identifying the channel, the channel data being in a machine readable format to be scanned by the bar code scanner of the personal digital assistant. Coffman does not disclose a channel of an infusion pump having a label containing channel data identifying the channel.

Claim 48 requires, among other things, that "the medication delivery device has multiple channels, each channel having a third label containing channel data identifying the channel, the channel data being in a machine readable format to be transmitted to the handheld computing device." Coffman does not disclose a channel of an infusion pump having a label containing channel data identifying the channel.

Claim 49 requires, among other things, that "the catheter having a fourth label containing catheter data identifying the catheter, the catheter data being in a machine readable format to be transmitted to the handheld computing device." Coffman does not disclose a catheter having a label containing catheter data.

Based on these distinctions as well, claims 27, 48, 49 should be allowable.

**b. Rejection of claims 4, 6-8, 12, 19-23, 34, 36, 39, 40, 41 and 53
under 35 U.S.C. § 103(a)**

The Examiner has rejected 4, 6-8, 12, 19-23, 34, 36, 39, 40, 41 and 53 under 35 U.S.C. § 103(a) as being unpatentable over Coffman in view of Lester. In support of these rejections, the

Examiner contends that Coffman teaches the Applicants invention except for a two dimensional bar code, and that Lester teaches a two dimensional bar code. Therefore, according to the Examiner, it would have been obvious to one of ordinary skill in the art at the time the invention was made for Coffman to have used a two dimensional bar code instead of a one dimensional bar code because, according to Lester, a two dimensional bar code is preferable based on its ability to contain more information in the same amount of space as a one dimensional bar code.

The Applicants respectfully traverse the Examiner's rejection.

Based on the shortcomings of Coffman as a primary reference, the Examiner has failed to present a prima facie case of obviousness. Coffman fails to disclose, among other things, a handheld device that reads medication delivery instructions from a tag or label and transmits them to a medication delivery device to deliver the medication to the patient. Thus, even if Coffman and Lester were combinable as the Examiner suggests, one still does not arrive at the Applicants' claimed invention.

Furthermore, the Examiner has failed to indicate a specific reference in either Coffman or Lester that would give one skilled in the art the motivation to combine the references as suggested by the Examiner. Accordingly, the Examiner has failed to make a prima facie case of obviousness.

Based at least on the foregoing, the Applicants submit that claims 4, 6-8, 12, 19-23, 34, 36, 39, 40, 41 and 53 are allowable over the cited art.

7. Claims 54-58

Due to an apparent oversight or typographical error, the Examiner did not include claims 54-58 in the rejections set forth in the present office action. Regardless of the reason for their omission, the Applicants submit that these claims are allowable for at least the same reasons as set forth above with respect to the independent claims. Allowance of these claims is respectfully requested.

CONCLUSION

In light of the foregoing amendments and remarks, the Applicant submits that claims 1-58 are in condition for allowance. Favorable reconsideration and allowance of the present application and all pending claims are respectfully requested. If, in the opinion of the Examiner, a telephonic conference would expedite the examination of this matter, the Examiner is invited to call either of the undersigned attorneys at (312) 554-3300.

Respectfully submitted,

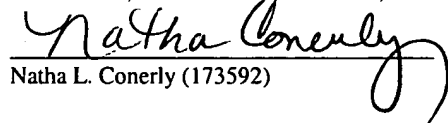


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